EXHIBIT H

The use of synthetic mesh in female pelvic reconstructive surgery

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KEYWORDS

prolapse, stress urinary incontinence, cystocele, colpopexy, vaginal surgery

INTRODUCTION

Pelvic surgeons are faced with a population of patients with an increasing life-expectancy; they can therefore anticipate that more women will present with pelvic floor disorders needing surgical correction. As nearly 30% [1] of women who undergo surgery to correct pelvic organ prolapse (POP) need re-operation, it is imperative that the surgical outcomes are improved. The major challenge facing pelvic reconstructive surgeons is to devise procedures which provide a durable correction of POP and incontinence, while minimizing morbidity. Several lines of research suggest that the tissues of the pelvic floor used in reconstructive procedures are themselves altered and weakened in women with POP and incontinence. Whether those tissue alterations are primary or secondary to the pelvic floor disorder remains unknown. For example, in women with POP after menopause, there is a reduction in the collagen type I : type III ratio [2] that might adversely affect the tensile strength of pelvic tissues. Similarly, postmenopausal women with stress urinary incontinence (SUI) have biomechanical alterations that weaken the tensile strength and elasticity of pelvic floor tissues [3]. These connective tissue alterations might eventually lead to the failure of the most technically sound incontinence or POP repair. To improve outcomes, it therefore seems reasonable to incorporate biomaterials to augment and reinforce pelvic floor repairs.

Currently available biomaterials include autografts (grafts from the host), allografts (human tissues from another host), xenograft (tissues from another species) and synthetic materials. There is considerable debate about which graft type is most suitable for transvaginal implantation in pelvic surgery. This uncertainty arises because there is little high-quality published information to guide the choices. The ideal biomaterial is inert, sterile, durable, not carcinogenic, and causes no inflammatory or immune reaction. In addition, it is inexpensive, readily available and easy to use [4]. None of the currently available graft materials fulfil the 'ideal', but we are learning more about the characteristics of these materials that make them suitable for pelvic reconstruction. Here, we review the characteristics and performance of synthetic meshes used in pelvic reconstructive surgery.

CLASSIFICATION OF SYNTHETIC GRAFT MATERIALS AND SELECTION OF MESH FOR UROGYNAECOLOGICAL SURGERY

There are several commercially available synthetic graft materials. The major advantage of synthetic graft materials is that they have no potential for infectious disease transmission. In addition, most are permanent materials that are readily available and relatively cost-effective. When comparing these materials, it is important to know about the characteristics of the mesh, as these qualities determine the biocompatibility of the mesh. The characteristics of the mesh materials that one must identify before implantation are as follows:

ABSORBABLE VS NONABSORBABLE

The most commonly used absorbable meshes, polyglactic acid (Vicryl, Ethicon, Somerville, NJ, USA) and polyglycolic acid (Dexon, Davis and Geck, Danbury, CT, USA) dissolve in 30–90 days. These materials have not been shown to promote infection, and have a low erosion rate. However, their rapid loss of tensile strength might limit their advantage in pelvic reconstructive surgery. In the treatment of SUI and vaginal vault prolapse, several authors have correlated higher failure rates associated with a breakdown of biological graft materials [5,6]. Based on these observations, the routine use of absorbable mesh material in gynaecological surgery must be questioned.

MACROPOROUS VS MICROPOROUS

Synthetic meshes are characterized on the basis of pore size; those of >75 μm are known as 'macroporous', whereas those <10 μm are 'microporous'. The 75 μm pore size is significant, as this has been reported to be the required pore size for the admission of macrophages, fibroblasts, blood vessels and collagen fibres into the pores [7]. This is thought to greatly lower the infection risk of graft materials. Birch and Fynes [8] noted that the size of leukocytes and macrophages is 9–20 μm, so that these cells can traverse pore sizes of <75 μm. Perhaps the greater utility of a larger pore size is the promotion of host-tissue ingrowth. More rapid infiltration of host tissue into the graft promotes long-term biocompatibility, theoretically rendering the graft material less likely to elicit complications.

MULTIFILAMENT VS MONOFILAMENT

The structure of the mesh composite is also important. A multifilament mesh has interstices within the filamentous fibres which are <10 μm. Bacteria can be very small (1 μm) and can replicate within the interstices of multifilament fibres. Extremely small pores might prevent access to host immune cells and diminish the ability of the host to combat bacterial colonization of the graft. Monofilament meshes do not have these small interstices, and theoretically have less risk of infection.

Synthetic mesh material has been classified on the basis of pore size and the filamentous nature of the material [9]. As outlined in Table 1, Type I mesh is macroporous and monofilament; type II mesh is microporous with pores of <10 μm; type III meshes are macroporous meshes with multifilamentous components (containing pores of <10 μm);

TABLE 1 The classification of synthetic biomaterials; adapted from Karlovsky et al. *[4]*

Synthetic material (manufacturer)	Filamentous structure	Mesh type	Pore size
Polypropylene, Marlex (CR Bard, Covington GA)	Monofilament	I	Macro
Polypropylene, Prolene (Ethicon, Somerville NJ)	Monofilament	I	Macro
Polypropylene, Atrium (Atrium Medical, Hudson NH)	Monofilament	I	Macro
Polypropylene, TVT (Johnson and Johnson, New Brunswick NJ)	Monofilament	I	Macro
Polypropylene, SPARC (American Medical Systems)	Monofilament	I	Macro
Polypropylene, Lynx (Boston Scientific, Natick, MA)	Monofilament	I	Macro
Polypropylene, T-Sling (Caldera Medical, Augura Hills, CA)	Monofilament	I	Macro
PTFE (Teflon, CR Bard)	Multifilament	III	Micro
Expanded PTFE, Gore-Tex (W.L. Gore, Flagstaff AZ)	Multifilament	II	Micro
Polyethylene tetraphthalate, Mersilene (Ethicon)	Multifilament	III	Macro/micro
Polyester-silicone coated, Intemesh (American Medical Systems)	Multifilament	IV	Submicro
Polyglycolic acid, Dexon (Davis and Geck, Danbury CT)	Multifilament	Absorbable	Macro
Polyglactin 910, Vicryl (Ethicon)	Multifilament	Absorbable	Macro

type IV meshes are 'coated' biomaterials that contain pores of <1 μm.

When considering the principles of preventing infection and host-tissue integration, it seems clear that theoretically one would favour implantation of a Type I synthetic mesh. These macroporous, monofilament meshes (polypropylene) promote the most rapid host tissue infiltration and host defence mechanisms, with the large pore size reducing stiffness of the material and allowing easier incorporation into reconstructive procedures.

Early experience with Type II and Type III synthetic meshes in pubovaginal sling and prolapse surgery was associated with significant mesh complications. Erosion rates of 20–30% were reported in patients after implantation of Dacron, Mersilene, and Marlex mesh materials [10,11]. In these earlier procedures, larger incisions with more extensive dissection might have increased the potential for infectious exposure, and increased tension might have promoted tissue ischaemia. The woven, multifilamentous nature of these mesh materials might have limited host-tissue ingrowth, leading to erosions, draining sinuses, and fistulae. This early experience forced many surgeons to abandon the use of synthetic material in pelvic reconstructive surgery.

The success of the tension-free vaginal tape (TVT) procedure introduced surgeons to several principles which facilitate the safe usage of synthetic material in pelvic reconstruction. The use of small incisions and minimizing dissection decreases the potential for bacterial exposure. The avoidance of tension on the mesh material prevents local tissue ischaemia, and the use of macroporous monofilament mesh materials promotes host-tissue ingrowth and biocompatibility. Incorporating these principles, the synthetic tension-free slings have become one of the more commonly used procedures in the surgical management of SUI. The incidence of mesh erosions and complications appears to be quite rare, despite its widespread use.

USE OF SYNTHETIC MESH FOR UI SURGERY

Ever since autologous fascia slings were described [12,13] surgeons have sought alternative sling materials to avoid the need to harvest autologous tissue; Nylon mesh slings were described in 1961 [14], followed by Mersilene slings in 1966 [15]. Synthetic materials were increasingly used by pelvic surgeons until in the 1980s reports of mesh complications began to appear, including mesh erosion into urethra or bladder [16], sinus tracts and fistulae [17]. During the latter half of the 1990s the autologous fascia sling then enjoyed a brief revival in popularity [18] before the introduction and popularization of allograft [19,20] and xenograft sling materials that avoid both the morbidity associated with the harvest of autologous tissue and some of the risks associated with the use of synthetic materials. Again, initial great enthusiasm for allograft and xenograft materials was soon tempered with questions about the durability of those materials, with early failure rates noted by several authors [21,22] but not confirmed by other, equally careful researchers. With the immense popularity of a variety of still newer, synthetic, mid-urethral synthetic slings, it is probably fair to say that controversies about allograft and xenograft materials are currently relegated to the background.

The TVT sling (Ethicon, Princeton, NJ, USA) is the prototype of this newer class of synthetic slings, developing from the intravaginal slingplasty procedure [23] designed according to the principles of the 'integral theory' [24]. Initial promising results with TVT prompted several manufacturers to market similar, minimally invasive mid-urethral sling devices using their synthetic and allograft mesh materials. Further innovation and concerns with retropubic complications of TVT and other similarly placed mid-urethral sling tapes (e.g. Sparc, Monarc, BioArc, from American Medical Systems), prompted the development of the transobturator approach [25] to the mid-urethral sling, which has recently gained immense popularity. The clinician can now choose from a wide range of mid-urethral sling materials that are passed either suprapubically or through the obturator membrane.

There is now published information about the medium-term success rate of TVT slings, but as yet there is only information about the early (1–2 year) success rates of other mid-urethral slings. The reader is referred to the excellent review by Atherton and Stanton [26] of the TVT for a full description of the results and complications of the TVT. In brief, TVT success rates vary according to definition, but

it is reassuring that at least in the few available case series, the short-term, high success rates of 87–91% [27–29] and low erosion rates of TVT slings are maintained over time [30,31]. In their 7-year follow-up case series, Nilsson *et al.* [32] reported objective and subjective cure rates of 81% at a mean of 91 months after TVT. As always, results of observational case series should be viewed with caution. Just one large, randomized comparative study of TVT with another continence procedure was published, and showed TVT success rates equivalent to open Burch colposuspension [33].

Only short-term results are available for mid-urethral slings placed through the transobturator route, but suggest that outcomes are comparable to those of the retropubic procedures [34,35] and are associated with significantly lower rates of bladder perforation. Longer-term results and prospective comparison studies are awaited.

USE OF SYNTHETIC MESH FOR ABDOMINAL SACRAL COLPOPEXY (SCP)

There is good evidence to support the use of nonabsorbable synthetic mesh material when performing abdominal SCP. The results of several randomized trials indicate that SCP with synthetic mesh provides better anatomical results than vaginal surgery using sacrospinous ligament fixation [36–38]. Whether this is because of the use of synthetic mesh or because of inherent differences in the postoperative vaginal axis or method of fixation between the procedures is unknown. A recent systematic review of 98 articles on SCP showed success rates for apical support of 78–100% and support of all segments of 58–100% [39]. The use of synthetic mesh rather than a biological graft to bridge the vagina to the sacrum is supported by a recent randomized trial by Culligan *et al.* [40], that compared cadaveric fascia lata to polypropylene mesh for SCP. At 1 year after surgery, the objective cure was better in the synthetic mesh group (91% cure) than in the cadaveric fascia lata group (68% cure; $P = 0.007$). There were significant differences in favour of the polypropylene mesh group at POPQ points Aa and C, as well as overall prolapse stage. Fitzgerald *et al.* [21] also noted poor anatomical outcomes when freeze-dried, irradiated donor fascia lata was used for SCP. Of 67 women who had SCP with this material, 83% of those who followed were failures by 17 months. In 16 patients who had a repeat SCP by these authors, no graft was found between the sacrum and vagina in 13. While these data support the view that synthetic mesh is better than biological grafts for SCP, there are no data available that compare the anatomical or functional results of different synthetic materials.

TABLE 2 Studies of anterior vaginal wall prolapse repair with nonabsorbable mesh

Reference	Mesh	N	Follow-up, months	Success rate, %*	Vaginal erosions %
Julian [43]	Marlex	12	24	12/12	8.3
Nicita [44]	Polypropylene	44	14	93.2	2.3
Flood *et al.* [45]	Marlex	142	36	94.4	1.4
Mage [46]	Metsuture†	46	26	100	2.2
Migliari and Usai [47]	Mixed fibre‡	15	23	93	0
Migliari *et al.* [48]	Polypropylene	12	20	9/12	0
Hardiman *et al.* [50]	Polypropylene	18	1.5	100	11.1
Salvatore *et al.* [51]	Polypropylene	32	17	87	13
de Tayrac *et al.* [49]	Polypropylene	87	24	91.6	8.3
Milani *et al.* [52]	Polypropylene	32	17	100	13

**Definitions of success and surgical technique vary among studies; †Ethicon, Issy-Les-Moulineaux, France; ‡60% polyglactin 910 and 40% polyester.*

USE OF SYNTHETIC MESH FOR VAGINAL RECONSTRUCTIVE SURGERY

In an attempt to improve the anatomical cure rates of transvaginal prolapse repairs, many surgeons have begun augmenting traditional prolapse repairs with biological or synthetic grafts. Unfortunately, this has been done largely without the benefit of data to support this practice. Two clinical trials compared augmentation with absorbable mesh (polygalactin 910, Vicryl) to traditional transvaginal repairs. Weber *et al.* [41] found that augmentation with absorbable mesh did not improve the anatomical results, while Sand *et al.* [42] reported less recurrence of anterior vaginal prolapse when Vicryl mesh was used. The available data on the use of permanent synthetic mesh are sparse and largely consist of small retrospective series with a short-term follow-up. Series vary in the type and size of graft used, location of implantation in the vaginal wall, location of lateral attachments of the graft, and whether the graft is secured with suture or 'tension-free.' There are currently no clinical trials comparing vaginal reconstructive surgery with synthetic mesh to traditional surgical repairs without grafts.

The available studies investigating the use of synthetic mesh in vaginal prolapse surgery have largely focused on the treatment of anterior vaginal prolapse. Table 2 [43–52] summarizes the currently available studies investigating this practice. In general, these uncontrolled case series report high anatomical cure rates with relatively high mesh erosion rates. The three most recent studies evaluating the use of polypropylene mesh to augment the surgical correction of anterior vaginal prolapse report an erosion rate of 8.3–11% [49–51]. There are few reports of graft augmentation in the posterior vaginal wall. Similarly, data on the effect of graft augmentation on bowel, bladder and sexual function are limited. Milani *et al.* [52] reported a prospective observational cohort of 63 women who had conventional anterior (32) or posterior (31) colporrhaphies augmented with polypropylene mesh. Both groups had excellent anatomical outcomes at 12 months after surgery (94% Stage 0), but there was a significant increase in the rate of dyspareunia. Of those who had an anterior repair with mesh, 20% had worsening dyspareunia after repair, while 63% of those who had a posterior repair with mesh developed worsening dyspareunia. The rate of mesh erosion in the anterior group was 6.3% and in the posterior group was 13%. These authors concluded that while this study showed good anatomical results with the use of Prolene mesh for vaginal prolapse repair, the morbidity rate was high and the authors

suggested that the use of Prolene mesh in vaginal reconstructive surgery be abandoned [52].

Despite the paucity of data, there is increasing adoption of tension-free vaginal mesh procedures involving procedural kits which include disposable insertion needles, retrieval devices, and large pieces of polypropylene mesh. Those available at present include Anterior, Posterior, and Total Prolift (Gynecare, Somerville, NJ, USA) and Apogee™ and Perigee™ (American Medical Systems, Minnetonka, MN, USA). Analysis of the first 100 tension-free vaginal mesh procedures revealed a 17.5% erosion rate, which fell to 2.7% with the avoidance of T-shaped colpotomies, concomitant hysterectomy, and perineal incisions [53].

While there is the potential that synthetic graft augmentation will improve the anatomical results of conventional surgical repairs, this must be balanced against increased morbidity and cost. The WHO 3rd International Consultation on Incontinence [37] recently concluded that 'transvaginal placement of permanent mesh may reduce anterior wall recurrence but has an unacceptably high rate of complications that include erosion, infection, sepsis, dyspareunia and other functional symptoms.' Because of this poor risk/benefit ratio, the Consultation recommended that these materials only be used in approved clinical trials and not be used in general clinical practice until more data are available. There is an urgent need for randomized trials comparing the anatomical and functional outcomes of traditional vaginal procedures to graft augmented repairs and to the newly marketed 'prolapse kits' that implant large pieces of polypropylene mesh vaginally.

COMPLICATIONS ASSOCIATED WITH SYNTHETIC MESH

Since they were first used in urogynaecological surgery, organic and synthetic meshes have been recognized as associated with a complication rate that can be minimized but not completely eliminated. Mesh erosion after SCP and suburethral sling was reported to occur in 2–9% of cases [54–58] and probably depends on the type of mesh used, although no mesh material has been found to be free of complications. While erosions can and do occur after implantation of organic meshes, those erosions seem to be less clinically morbid. A synthesis of the currently available reports noted that the reported erosion rate for polypropylene is 0.5%, for polyethylene terephthalate (Mersilene, Johnson & Johnson) is 3.1%, for Gortex (WL Gore & Associates, Flagstaff, AZ, USA) is 3.4%, Teflon (E.I. DuPont de Nemours and Co., Wilmington, DE, USA) is 5.6% and for polyethylene (Marlex, CR Bard, Haverhill, MA, USA) is 5.0% [39]. The method of graft placement appears to have an effect on mesh erosion rates. Visco *et al.* [58] retrospectively analysed Mersilene mesh erosion rates in 273 women who had had SCP or sacral colpoperineopexy; the overall risk of erosion was 3.2% for abdominal SCP and 4.5% for sacral colpoperineopexy (introducing the graft and sutures abdominally). Erosion increased to 16% if sutures were placed vaginally and attached to an abdominally introduced mesh during sacral colpoperineopexy. If mesh was introduced vaginally, the erosion rate peaked at 40%. The median times to mesh erosion were 15.6, 12.4, 9.0 and 4.1 months, respectively. Some authors found that concurrent hysterectomy is a risk factor for mesh erosion after SCP [58,59], while others have not [41,56]. Mesh erosions after SCP typically occur at the vaginal apex and can usually be managed by a transvaginal excision of the exposed mesh with primary closure of the defect [58]. Removing eroded or infected mesh abdominally should be avoided unless absolutely necessary because of increased risk of complications, particularly life-threatening haemorrhage [60].

No reader will be surprised to learn that the real rate of mesh complications associated with synthetic and organic meshes is unknown. Although there is a mechanism for reporting adverse events associated with meshes and other medical devices, reporting is not mandatory and it is unclear with whom the responsibility for reporting lies. Informal polling of our colleagues suggests that formal reporting of mesh complications to the USA Food and Drug Administration (FDA) is very rare. Furthermore, because the FDA does not require proof that a new mesh material is safe or effective in humans before allowing its marketing to the public (the manufacturer simply has to show evidence that their new mesh is essentially equivalent to a mesh that is already FDA-approved), some mesh materials have come to market that were unsuitable for the use in urogynaecological surgery. For example, the ProtoGen sling was on the market from March 1997 until its voluntary recall in January 1999. This was a woven polyester sling injected with bovine collagen, and was associated with an unacceptably high rate of vaginal erosion [61]. More recently, some concern has arisen about a relatively high erosion rate (17%) seen with the intravaginal slingplasty (American Medical Systems) sling material [62], the InteMesh (American Medical Systems) sling material which eroded in two of 10 slings placed in one series [63], and Prolene (Ethicon) mesh which eroded in 6.5% of women in whom it was placed during vaginal prolapse repair [52]. These initial concerns remain to be confirmed by larger case series.

Indeed, there is very little information on factors that influence mesh erosion rates; the limited information suggests that all meshes are not the same and it is wise to wait for longer-term outcome information in a large series of patients before adopting a new mesh material. Until such information is available, newer meshes should be evaluated formally, within the context of a clinical trial.

In brief, results of several larger case series suggest that usually the complications associated with TVT are minor and cause no long-term morbidity. For example, a survey of 38 hospitals in Finland, where 1455 TVT procedures were performed, noted an incidence of recognized intraoperative bladder perforation of 3.8%, major vessel injury 0.07%, nerve injury 0.07%, and urethral lesion 0.07% [64]. Minor voiding difficulty occurred in 7.6% and defective vaginal defect healing was present in 0.7%. Similarly, in a large cohort of 809 TVT patients from the Netherlands [65], there was intraoperative bladder perforation in 3.5% of patients, iliac vessel injury in 0.1%, and tape erosion in 0.2%. In the USA, Karram *et al.* [66] similarly reported that among 350 women, 4.9% had bladder perforation, 4.9% had postoperative voiding dysfunction, 0.9% had erosion or poor vaginal healing, and nerve injury occurred in 0.9%. Finally, the Austrian TVT registry reported on complications of 806 procedures, noting bladder perforation in 4% of patients [67].

Notably, several deaths have been associated with the use of TVT. In Gynecare's report of complications reported to them from >500 000 patients treated with TVT, there were 44 (0.009%) vascular injuries (including two associated deaths), 20 (0.004%) urethral

erosions, 28 (0.006%) bowel perforations (including three associated deaths) and four nerve injuries. The USA FDA Manufacturer and User Facility Device Experience database (www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/search.cfm) website also tracks complications reported to them. Searching the site using the keyword 'tension-free vaginal tape' yielded 802 reports between 1998 and 2005 (while all of these adverse events were associated with a TVT procedure, not all are attributable to the device itself). Recent searching the site using the keyword 'TOT' yielded just four reports, using keyword TVT-O yielded no reports, but a search using 'Obtape sling' yielded 156 reports to the FDA in 2004–2005. Again, not all of these adverse event reports will be due to the device itself.

MANAGEMENT OF SYNTHETIC MESH EROSIONS

Known symptoms of mesh erosion into the bladder/urethra include dysuria, urgency, frequency, haematuria, recurrent UTIs, urinary calculi and symptoms of continuous leakage when a fistula has resulted. When mesh has eroded into the bladder, urethra or bowel it must be removed. In many cases, endoscopic resection of eroded mesh is possible, with good results.

When mesh erodes into the vagina, it usually does not cause the patient pain, but does result in malodorous vaginal discharge, vaginal bleeding or postcoital spotting. The patient's sexual partner may also sense a foreign body within the vagina, causing some discomfort to the partner. The management of mesh erosion into the vagina depends on the type of mesh and on the size of the erosion. Some small erosions (no more than a few millimetres) can be conservatively managed with vaginal rest and administration of vaginal oestrogens, and will become covered with vaginal mucosa over the course of a few weeks. Larger erosions of mid-urethral slings are not likely to resolve, and must be excised either in the office setting or formally, in the operating room. The astute practitioner who finds a vaginal mesh erosion will also use cystoscopy to check for simultaneous erosion into urethra or bladder. Continence rates after resection of eroded mid-urethral slings are unknown.

Similarly, very small (1–2 mm) erosions of large-pore SCP meshes can resolve over time with vaginal rest and administration of oestrogen creams. Indeed, it is not known whether such erosions would resolve without the use of oestrogen creams, but this is not likely to be tested by a formal clinical trial. In our experience, even the smallest of Gore-Tex SCP erosions do not usually resolve.

Larger SCP mesh erosions require resection and closure of the vaginal mucosa, and must usually be done in the operating room; it is accomplished relatively easily by widely mobilizing the vaginal mucosa surrounding the erosion, excising all accessible mesh and closing the vaginal mucosa using absorbable suture. In most circumstances, when a relatively small amount of SCP mesh is removed the scar that has formed around the mesh acts to continue support of the vagina and POP does not recur. However, when most or all of the mesh is removed because of erosion, it is our experience that POP recurs during the subsequent 1–2 years.

CONCLUSIONS

Surgical innovation certainly continues in the field of female pelvic reconstructive surgery. Clinicians are now well aware that there is a low, apparently irreducible rate of mesh erosion associated with the use of even the newest synthetic meshes for reconstructive and incontinence surgery. We will probably never know the true erosion/complication rate, but apparently the clinical impression is that the results of synthetic mesh use for SCP and suburethral sling procedures justify the associated erosion rate. We all hope that continuing developments in the manufacture of synthetic meshes will produce the 'ideal' mesh material for use in our surgical discipline. We encourage all pelvic surgeons to avoid adopting newer meshes and procedures until their advantages and disadvantages have been explored within the context of formal surgical trials. It is only when we remain judicious and withhold implantation of unproven mesh materials that manufacturers will be forced to allocate appropriate resources to truly demonstrate that these materials represent an advance for our patients.

CONFLICTS OF INTEREST

None declared.

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Abbreviations: **POP**, pelvic organ prolapse; **(S)UI**, (stress) urinary incontinence; **TVT**, tension-free vaginal tape; **FDA**, Food and Drug Administration; **SCP**, sacral colpopexy.

Editorial comment: The use of synthetic mesh in female pelvic reconstructive surgery

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The use of meshes in pelvic reconstructive surgery for both urinary incontinence (UI) and urogenital prolapse has become very popular in recent years. Various different materials are currently being used, both biological and synthetic grafts, but unfortunately with minimal evidence of efficacy and poorly reported complication rates.

Winters *et al.* [1] explain the perceived need for meshes to reinforce inherently weak connective tissue in women with UI and urogenital prolapse. They describe the various different types of grafts, comparing absorbable and nonabsorbable synthetic materials, macroporous and microporous meshes, multifilament and monofilament weaves, and explain that macroporous monofilament meshes such as polypropylene are associated with the lowest infection and erosion rates. They explain that this type of mesh is used in the TVT procedure, which has been shown to be both effective and relatively safe. Whilst there are now reported data up to 7 years relating to TVT insertion, the same is not true for the multitude of other mid-urethral slings which are now available both for retropubic and transobturator use.

Synthetic mesh has also been used successfully for abdominal sacrocolpopexy and has been shown to be better than biological grafts for this purpose. However, the use of synthetic weaves in vaginal reconstructive surgery is relatively new and there are now commercially made 'kits' available to facilitate insertion of large sheets of mesh into the anterior and/or posterior compartment of the vagina, advocated for the repair of all three compartments of the pelvis.

The first reported series of 100 patients showed a 17.5% erosion rate. However, this was significantly reduced by avoiding a 'T' colpotomy incision and by leaving the uterus *in situ* in women who had not previously had a hysterectomy. No explanation or justification has been given for this and there must be some concern about the possible need for a future hysterectomy in women who have had a total vaginal mesh insertion. Would it be possible to undertake a vaginal hysterectomy or would it need to be performed abdominally, and what would be the new possibly unforeseen complications? The authors [1] carefully identified the many possible complications associated with the use of synthetic meshes and suggested ways in which these complications can be successfully managed.

Winters *et al.* [1] did not mention the use of biological or synthetic meshes in association with other surgical interventions in different specialities, and this might be relevant, as general surgeons have used polypropylene mesh for hernia repairs for many years, on the basis that the recurrence rate has been shown to be less than conventional repair in the large European randomized control trial.

What the authors have done is to stress the need for proper trial data before introducing meshes into reconstructive pelvic surgery. They have quoted the 3rd International Consultation on Incontinence, which took place in Monaco in 2004, and that recently concluded that 'transvaginal placement of permanent mesh may reduce anterior wall recurrence but has an unacceptably high rate of complications that include erosion, infection, sepsis, dyspareunia and other functional symptoms'. The risk of dyspareunia in association with any pelvic floor surgery is particularly worrying, as it is often under-reported, despite both traditional pelvic floor repair including levator plication and the more recent mesh repairs, both being associated with an unacceptably high dyspareunia rate. That a woman is not sexually active at the time of her pelvic floor surgery does not mean that she would never wish to be so in the future, and the possibility that she may never be able to have satisfactorily penetrative sexual intercourse again needs to be fully explored.

This balanced overview appropriately cautions us to remain judicious and withhold implantation of unproven mesh materials until manufacturers have confirmed their efficacy and safety. It is well written, up to date and appropriately referenced, and I commend it to you.

CONFLICTS OF INTEREST

None declared.

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Abbreviations: **UI**, urinary incontinence.